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JUN 19 2012

Summary of Safety and Effectiveness

Date: March 23, 2012

Manufacturer:
Encore Medical, L.P.
Trade Name: DJO Surgical
9800 Metric Blvd
Austin, TX 78758

Contact Person:
William Garzon
Regulatory Affairs Specialist
Phone: (512) 834-6391
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Email:
william.garzon@djoglobal.com

Product	510(k) Number, Clearance Date/ Classification	Product Code	Classification Name
Linear Porous Coated Hip Stem, Size 5	K991325 – June 25, 1999, Class II	LPH	Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis per 21 CFR 888.3358
Revelation Hip Stem, Size 8	K994070 – January 20, 2000, Class II	LPH	Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis per 21 CFR 888.3358
Foundation Porous Press Fit Stem, Size 8	K991226 – June 1, 1999, Class II	LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353
Foundation Cemented Hip Stem, Size 10.5 - 18	K952191 – July 17, 1995, Class II	JDI, JDG	Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350
Foundation Cemented Stem, Size 8	K991227 – June 1, 1999, Class II	JDI	Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350
Foundation Cemented Stem, Size 9	K961890 – June 14, 1996, Class II	JDI	Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350

Description: The modification consists of a change to the Instructions for Use to minimize the necessity for multiple IFU's and to update the contents to reflect current practice.

Indications for Use: Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture;

This device may also be indicated in the salvage of previously failed surgical attempts.

The following Hip Stems are for Cementless application:

Linear Porous Coated Hip Stem, Size 5
Revelation Hip Stem, Size 8
Foundation Porous Press Fit Stem, Size 8

Summary of Safety and Effectiveness – cont.
DJO Surgical Hip Systems

The following Hip Stems are for Cemented application:

Foundation Cemented Hip Stem, Size 10.5 - 18
Foundation Cemented Stem, Size 8
Foundation Cemented Stem, Size 9

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same indications, sterilization, and intended use.

Non-Clinical Testing: None Provided

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Encore Medical, L.P.
% Mr. William Garzon
Regulatory Affairs Specialist
9800 Metric Boulevard
Austin, Texas 78758

JUN 19 2012

Re: K121024
Trade/Device Name: Linear Porous Coated Hip Stem, Size 5
Revelation Hip Stem, Size 8
Foundation Porous Press Fit Stem, Size 8
Foundation Cemented Hip Stem, Size 10.5 – 18
Foundation Cemented Stem, Size 8
Foundation Cemented Stem, Size 9
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, JDI, JDG
Dated: March 27, 2012
Received: April 04, 2012

Dear Mr. William Garzon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K121024

Device Name: Linear Porous Coated Hip Stem, Size 5

Indications for Use:

Linear Porous Coated Hip Stem, Size 5
Indications for Use

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture;

This device may also be indicated in the salvage of previously failed surgical attempts. This stem is intended to be used in a cementless mode.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121024

510(k) Number (if known): K121024

Device Name: Revelation Hip Stem, Size 8

Indications for Use:

Revelation Hip Stem, Size 8
Indications for Use

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture;

This device may also be indicated in the salvage of previously failed surgical attempts. This stem is intended to be used in a cementless mode.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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and Restorative Devices

510(k) Number K121024

510(k) Number (if known): K121024

Device Name: Foundation Porous Press Fit Stem, Size 8

Indications for Use:

Foundation Porous Press Fit Stem, Size 8
Indications for Use

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture;

This device may also be indicated in the salvage of previously failed surgical attempts. This stem is intended to be used in a cementless mode.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number K121024

510(k) Number (if known): K121024

Device Name: Foundation Cemented Hip Stem, Size 10.5 - 18

Indications for Use:

Foundation Cemented Hip Stem, Size 10.5 - 18
Indications for Use

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture;

This device may also be indicated in the salvage of previously failed surgical attempts. This stem is intended to be used in a cemented mode.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number K121024

510(k) Number (if known): K121024

Device Name: Foundation Cemented Stem, Size 8

Indications for Use:

Foundation Cemented Stem, Size 8
Indications for Use

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture;

This device may also be indicated in the salvage of previously failed surgical attempts. This stem is intended to be used in a cemented mode.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number K121024

510(k) Number (if known): K121024

Device Name: Foundation Cemented Stem, Size 9

Indications for Use:

Foundation Cemented Stem, Size 9
Indications for Use

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture;

This device may also be indicated in the salvage of previously failed surgical attempts. This stem is intended to be used in a cemented mode.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number K121024